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10/759,605	01/20/2004	Jan Weber	12013/51401	8100

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/759,605

Applicant(s)

WEBER ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,12,14-20,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9-11,13,21,22 and 25-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/20/04, 11/18/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 6,8,12,14-20,23,24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/6/06. Applicant's traversal is on the grounds that search and examination of the entire application can be made without serious burden to the Examiner, in particular, because the same fields and subfields would be searched. Applicant's traversal has been carefully considered, but fails to establish error in the propriety of the present requirement for restriction and election.

Though Applicant asserts that examination of all pending claims would not pose an undue burden on the Examiner, such is not an accurate assertion in light of the disparate nature of the presently claimed subject matter as noted in the Requirement for Restriction of specie coatings.

Consideration of the plurality of inventions that Applicant has claimed would significantly compromise and preclude a quality examination on the merits. Furthermore, execution of a search encompassing the entirety of Applicant's coated medical devices would not only constitute an undue burden on the Examiner, but consideration of the findings of such a search in accordance with the requirements of the law under 35 U.S.C. §§101,102, 103 and 112 would be unduly onerous.

Moreover, it is further noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the classes and subclasses in which they are classified. Therefore, it is obvious that a comprehensive search of the copious amounts of patent and non-patent literature for each of the patentably distinct inventions and their permutations presently claimed would necessarily place an undue burden on the Examiner.

Therefore, for the reasons above and those made of record in the Requirement for Restriction of species, the restriction requirement is deemed proper and is made FINAL.

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **111**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: reference characters "110" and "112" have both been used to designate stent in paragraph 40.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim fails to define what high and low strain regions are defined by with regards to its structure. Additionally, it should be noted that not all devices are expandable. Claim 25 recites the limitation "expanded" in lines 2,3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not state the device is expandable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3738

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5,9,11,27,30 are rejected under 35 U.S.C. 102(e) as being anticipated by Noda et al. (6534197). Noda et al. disclose (Fig. 2) a medical implant having an implant body (D) with a catalyst (C) covering the entire first surface of the implant and between a filter material (A) that also covers the entire first surface. It has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Thus, the filter is “adapted to” retard travel of white and red blood cells. Noda et al. also disclose to treat the catalyst layer which increases its surface area, col. 6, lines 27-32. Noda additionally discloses the implant is a non-polymer, col. 3, lines 48,49.

Claims 1-5,9,11,13,25,26,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (6217607). Fig. 3 shows a stent substrate **15** having a catalyst coated **50** thereon and a filter layer **80** on the outer area. It has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Thus, the filter is “adapted to” retard travel of white and red blood cells. Fig. 1 shows a stent body with struts. Alt discloses

the stent is made of a non-polymer and covered with a catalyst metal, col. 7, lines 7,8.  
Alt discloses the outer filter is mesoporous or a ceramic-like material, col. 8, lines 6-10.

Claims 1-5,7,9,10,13,25,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson (5690670). Davidson discloses a medical implant with a body having a first surface covered with a catalyst such as titanium oxide, col. 7, lines 8-11. Davidson also discloses the stents can include a therapeutic agent, col. 14, lines 60-64 and col. 16, lines 48-52. Davidson also discloses that coatings applied to medical implants can be polymers and ceramics can be applied on the surface of the implant, col. 11, lines 59-66 and col. 12, lines 49-67. Davidson also discloses the use of a porous coating on the stent, col. 4, lines 56-66.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kula et al. (6325825). Figs. 1a-d,2,3a,b,4,6-9 all illustrate different strut patterns. Figs. 11,12 show that the stent has a tapered cross-section. It is inherent that a strut will have a smaller area for the areas toward the outside of the stent in locations where the stent has a smaller or tapered thickness. Kula also discloses the stent is expandable, col. 4, lines 15-18.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21,22,28,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. '607 in view of Smalley et al. (2002/85968). Alt et al. is explained supra. Alt does disclose the filter material can be iridium oxide, col. 7, lines 46-48. However, Alt et al. fail to disclose alternative filter material or coverings for the composite stent. Smalley et al. teach the use of catalysts with carbon nanotubes or bucky paper coated onto to composites including implants and prostheses, paragraphs 121,276. Smalley also teaches that the bucky paper is useful in supporting catalysts on devices (paragraph 126) and to provide a composite device resisting delamination, paragraph 14. Smalley additionally teaches the bucky paper can be used with oxides, paragraphs 94,166,268. Smalley also teaches that polymers can be applied to enclose the composite material and provide the bulk or support for the body framework, paragraphs 257,259. It would have been obvious to one of ordinary skill in the art to incorporate bucky paper and a polymer matrix as taught by Smalley et al. with the stent of Alt et al. such that it improves the adherence of the layers formed on the stent material and provide a supportive device that will not collapse or degrade.

Claims 34,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kula et al. '825 in view of Alt et al. '607. Kula et al. is explained as before. However, Kula fails to disclose the use of a catalyst and filter. Alt is explained supra. Alt discloses the outer coating layer or oxide aids in reducing inflammation, col. 10, lines 41-47. It would have been obvious to one of ordinary skill in the art to incorporate the catalyst




and filter material on the stent as taught by Alt et al. such that the stent of Kula et al. can provide a limited inflammatory response when implanted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (8:30am-5pm) .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

  
BRIAN E. PELLEGRINO  
PRIMARY EXAMINER